REMARKS

Claims 1-20 are pending in the present application. Of these, claims 1-9 are allowed. Claims 10 and 16-19 are rejected under USC 102(b) and 103(a). Claims 11-15 are objected to as being dependent upon a rejected base claim (claim 10), but are stated to be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims. Applicants are willing to consider such an amendment in the future, but for the present contend that claim 10 is properly patentable as argued herein.

Claim 10 is amended herein by the addition of a period at the end of the claim (the period having been previously omitted in error). Claim 20 is amended to correct a 35 USC 112, second paragraph rejection for indefiniteness due to lack of antecedent basis.

I. APPLICANTS' INVENTION

The present invention relates to a catheter balloon made of tube having a microstructure of nodes and fibrils such as porous expanded polytetrafluoroethylene (PTFE), further including a non-porous coating over the porous microstructure. The coating renders the balloon non-porous and thereby able to contain a desired inflating media (e.g., air or saline fluid). The thinness, flexibility and strength of the construction allow the resulting balloon to be collapsed to a small first diameter for insertion into a vascular conduit to a desired location at which it can be inflated to the maximum diameter of the tube in the fashion of a conventional polyethylene terephthalate (PET) catheter balloon. The balloon of the present invention is superior to such conventional balloons due to its flexibility, thinness, strength and lubricious materials.

II. REJECTION OF CLAIM 20 UNDER 35 USC 112, SECOND PARAGRAPH AS BEING INDEFINITE.

The Examiner points out that claim 20 recites the limitation "the non-porous coating" while claim 10 from which it depends does not include such a limitation. Claim 20 is amended herein to correct this lack of antecedent basis.

III. REJECTION OF CLAIMS 10, 16 AND 18-19 UNDER 35 USC 102(b) AS ANTICIPATED BY US PATENT 4,106,509 TO McWHORTER.

The Examiner states that McWhorter discloses a medical device comprising a tube having a node and fibril microstructure, the tube being non-porous and configured as an inflatable balloon, wherein the balloon is an inelastic balloon and wherein the balloon comprises a portion of a balloon catheter.

McWhorter teaches the construction of a balloon catheter comprising a tubular shaft having proximal and distal ends with an inflatable sleeve surrounding the distal end of the shaft, the inflatable sleeve constituting an inflatable balloon. As such, Applicants agree that the balloon of McWhorter comprises a portion of a balloon catheter. That said, there are fundamental differences between McWhorter and the present invention as described by instant claim 10 and dependent claims 16 and 18-19.

The catheter shaft of McWhorter is a tubular component of porous material that is pervious to air and impervious to body fluids (ref. no. 38 in Figures 1-3 and ref. no. 38' in Figure 4). It is this component that is described as being made of "Gore-Tex" (e.g., col. 3, lines 2-22) which has a known node and fibril microstructure. This catheter shaft, while "flexible," is of entirely different (e.g., relatively inelastic) character from the balloon component, ref. no. 28 and 29 of Figures 1 and 2, and ref. no. 28' of Figure 4 of McWhorter. This balloon material is stated to be elastomeric and is preferably elastomeric silicone rubber (col. 3, lines 37-39). The difference in the catheter shaft material and the balloon material of McWhorter is stated clearly in the last sentence of the abstract: "A longitudinally extending portion of the channel is formed from a porous material which is pervious to air and impervious to body fluids and which is not-wettable by body fluids, and *the inflatable sleeve comprises an elastomeric material other than the porous material.*" (Italics added.) It is apparent that the catheter shaft (including this "channel") of McWhorter is made from the porous material such as "Gore-Tex" with the node and fibril microstructure, while McWhorter's inflatable balloon is made from an elastomeric material that is entirely different from the "Gore-Tex" that makes up the tubular catheter shaft. Clearly, the catheter shaft of McWhorter is not configured as an inflatable balloon. Likewise, the "Gore-Tex" material taught by McWhorter for use as his non-inflatable catheter shaft is porous through its thickness (pervious to air) and as such does not suggest the tubular form of non-porous material having the node and fibril microstructure that is configured for use as the inflatable balloon of the present invention. The catheter shaft component and the balloon component of McWhorter have entirely different material characteristics. The elastomeric balloon sleeve of McWhorter clearly does not anticipate the present invention as described in claims 10, 16 and 18-19.

IV. REJECTION OF CLAIM 17 UNDER 35 USC 103(A) AS UNPATENTABLE OVER US PATENT 4,106,509 TO McWHORTER.

Claim 17, dependent to claim 10, adds a limitation specifying that the tube comprises multiple layers of porous expanded polytetrafluoroethylene (the "Gore-Tex" material referred to by McWhorter). This claim is non-obvious for the same reasons given above for claims 10, 16 and 18-19 being not anticipated by McWhorter.

CONCLUSION

The applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

If any questions remain, applicants request an interview prior to the next Office Action.

Respectfully Submitted,

Wayne D. House

Wayne D. House, 34,623
W. L. Gore & Associates, Inc.
551 Paper Mill Road, P.O. Box 9206
Newark, DE 19714-9206
(928) 864-2574

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